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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
09/30/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/569,160	ASMUSSEN ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 7-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 7-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 9, 11, 13-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 2 recites the broad recitation "the polymer content amounting to 5 to 95%", and the claim also recites "preferably 15 to 75%, with preference 20 to 50%" which is the narrower statement of the range/limitation. Claim 3 recites the broad limitation "within 30 minutes", and the claim also recites "within 5 minutes" which is

the narrower statement of range/limitation. Claim 9 recites the broad limitation "that the active substance content is 0.1 to 30%-wt", and the claim also recites "preferably 1 to 20%-wt" which is the narrower statement of range/limitation. Claim 11 recites the broad limitation "its layer thickness is 0.001 to 5 mm" and the claim also recites "preference 0.05 to 1 mm".

Claims 13-24 provide for the use of at least one cholinergic active agent acting on the central nervous system, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 13-24 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 25 and 26 are also rejected as being dependent on claim 13 a rejected use claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 7-9, 11, 12, 13 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Yang et al (US 2003/0107149 hereafter '149) in view of Gilis et al (USPN 6,099,863 hereafter '863).

The '149 patent discloses a thin oral film formulation comprising an active agent and a polymer [0017-0021]. The polymer is present in the film in a concentration up to 75% (Table 4). The active agents including drugs or flavors are present in an amount up to 15 mg and concentrations of about 3.5% [0115 and Table 4]. The films can be multilayered where at least one layer comprises the active agent [0132]. The films dissolve in the oral cavity, including the buccal, gingival and sublingual mucosa [0093, 0156]. The films dissolve quickly in an aqueous environment [0157]. However the film may comprise a layer that delays the release of the drug [0155]. The films have a thickness from 500 microns to 1500 microns [0152]. The film comprises fillers, colorants, plasticizers and the like [01174-0130]. Cholinesterase inhibitors can be included in the film formulation [0099].

The reference differs from the instant claims in that although cholinesterase inhibitors can be included in the formulation they are not specifically named by the '149 application. These

compounds are well known in the art, specifically in the art of orally dissolvable dosage forms. This can be seen in the '863 patent.

The '863 patent discloses a fast dissolving galanthamine formulation (abstract). The formulation comprises a carrier matrix where the active agent is present in an amount from 2 to 10%, with the support matrix up to 93% (col. 3, lin. 50-65). The support matrix includes a polymeric disintegrants as well as microcrystalline cellulose (***Ibid.***). The formulation comprises other excipients lubricants and fillers (Examples). The formulations dissolve in the oral cavity and begin to deliver their active payloads within 5 minutes (Example 6). The formulation can be used to treat chemical dependency, as well as Alzheimer's Dementia (col. 1, lin. 43-65). It would have been obvious to include the galanthamine salt of the '863 patent into the thin oral films of the '149 patent since the '149 reference is suggestive of cholinesterase inhibitors and discloses fast dissolving oral dosage forms. The combination would have been obvious following the suggestions of the '149 application and teachings of the '863 to quickly deliver the compounds orally. The combination would have been obvious to on of ordinary skill in the art in order delivery a quick relief to those suffering from chemical dependency.

One of ordinary skill in the art would have been motivated to combine the galanthamine salt of the '863 patent into the film composition of the '149 reference in order to quickly deliver the compounds to patients suffering from chemical dependency. The combination would have been obvious since both reference disclose oral delivery of cholinesterase compounds in compositions comprising similar amounts of the active agents and polymer matrix components. Both references also disclose similar carrier matrices comprising flavors, filers and plasticizers. Both formulation are designed to dissolve quickly to overcome the limitation of dosage forms

that require swallowing. It would have been obvious to combine the prior art with an expected result of a stable film formulation useful in treating chemical dependency.

Claims 1-3, 7-13, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Yang et al (US 2003/0107149 hereafter '149) in view of Gilis et al (USPN 6,099,863 hereafter '863) and Uekama et al (USPN 5,904,929 hereafter '929).

As discussed above the combination of the '149 and '863 patent would provide a buccal film formulation comprising cholinesterase inhibitors and a polymer matrix that dissolves quickly in the oral cavity. The combination is however silent o to further cholinesterase inhibitors, although the '149 suggests that these compounds can be present in the plural. It would be obvious to add additional similarly acting compounds to the formulation in order to increase the effectiveness of the dosage form. These other compounds are well known tine hart as seen in the '929 patent.

The '929 patent discloses oral formulations comprising a range of active agents including parasympathomimetics such as galanthamine, neostigmine and tacrine (col. 6, lin. 20-23). The dosage forms include trans-mucosal films, or tablets (col. 4, lin. 1-20). The formulation further comprises microcrystalline cellulose, and hydroxypropylcellulose (Example 13). It would have been obvious to add these other cholinesterase inhibiting compounds to the combination of the '149 and '863 films in order to increase the effectiveness. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. *See* In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

It would have been obvious to combine the other cholinesterase inhibitory compounds of the '929 patent into the combination of the '149 and '863 reference since each patent discloses a similar composition comprising the same active agents, in similar polymeric matrices that are all delivered orally. This combination would have been obvious in order to increase the effectiveness of the dosage form in treating chemical dependency. One of ordinary skill in the art would have been motivated to combine the prior art with an expected result of a buccal film useful in the treating chemical dependency.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618
/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618